

REMARKS/ARGUMENTS

In the specification, paragraph [0007] has been amended to include a brief description of FIG. 10 and FIG. 11 and to correct minor editorial problems. In paragraphs [0007], [0010], [0011], [0075], and [0078], all occurrences of Table 1, Table 2, and Table 3 have been replaced with FIG. 21, FIG. 22, and FIG. 23, respectively. These amendments make the specification consistent with the replacement drawing sheets included in the Reply to Notice to File Corrected Application Papers.

Please apply any charges not covered or any credits to Deposit Account 10-0750 (Johnson & Johnson).

Respectfully submitted,

Date: 4/2/2004

Adenike Adewuya
Adenike A. Adewuya
Reg. No. 42,254
Tel.: (281) 477-3450



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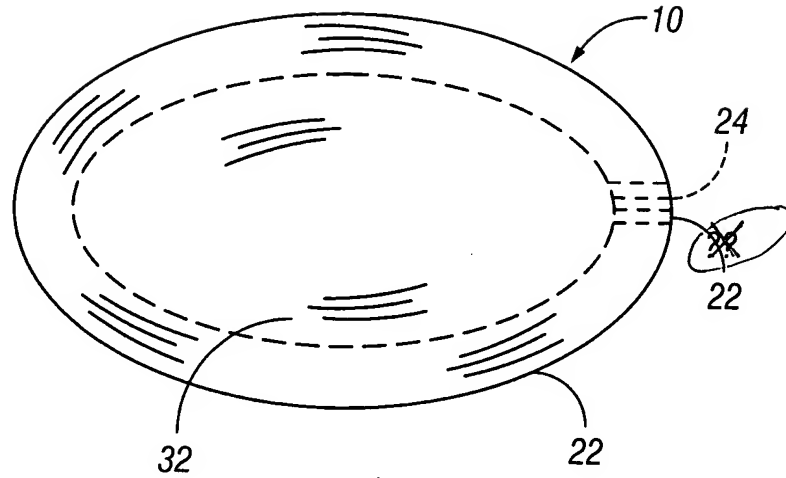


FIG. 10

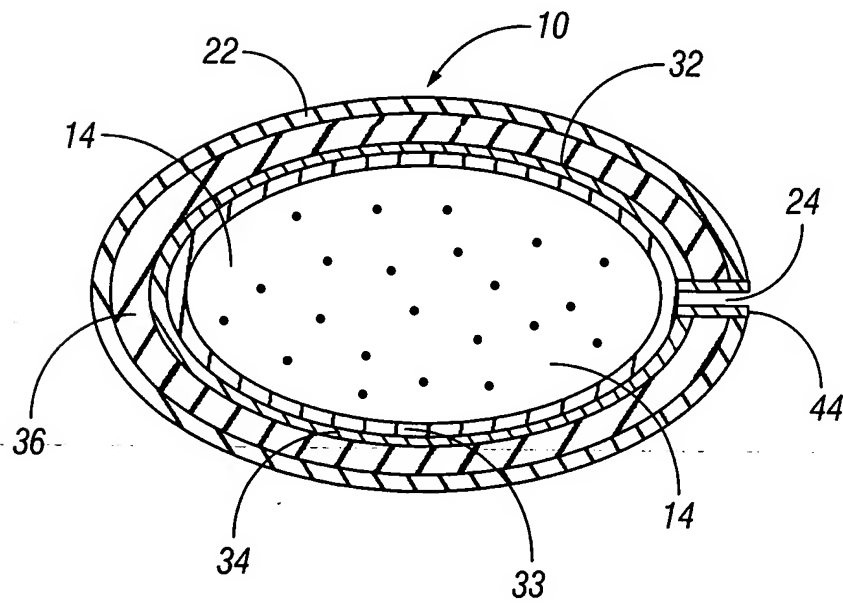


FIG. 11

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Solubility Enhancement, Nano vs Raw MGA

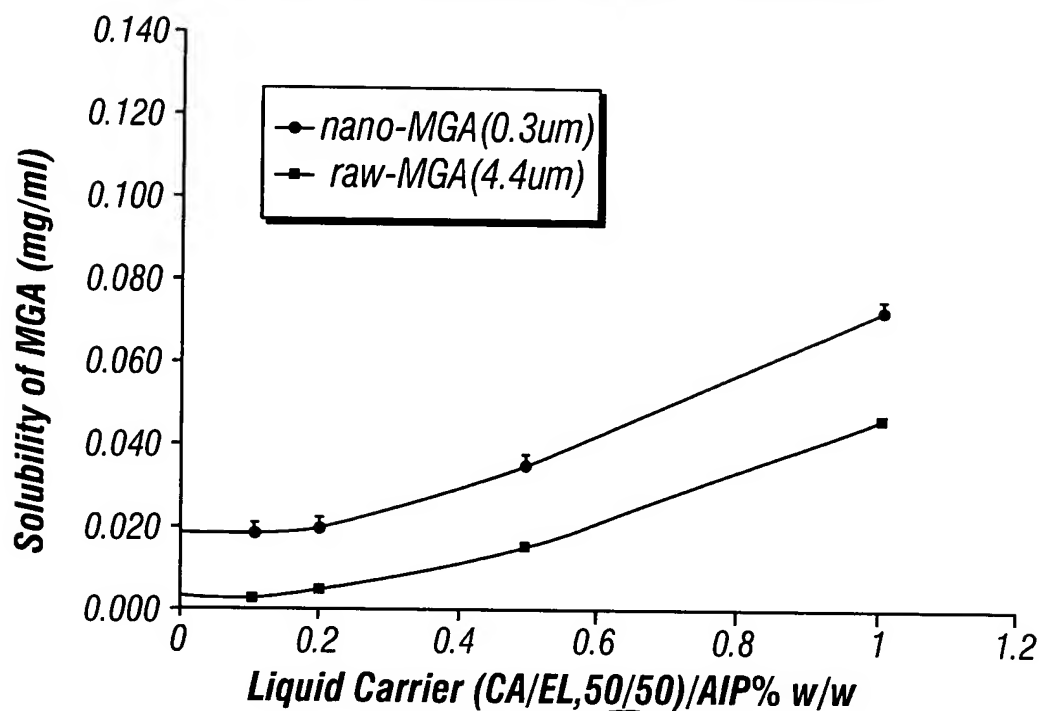


FIG. 16

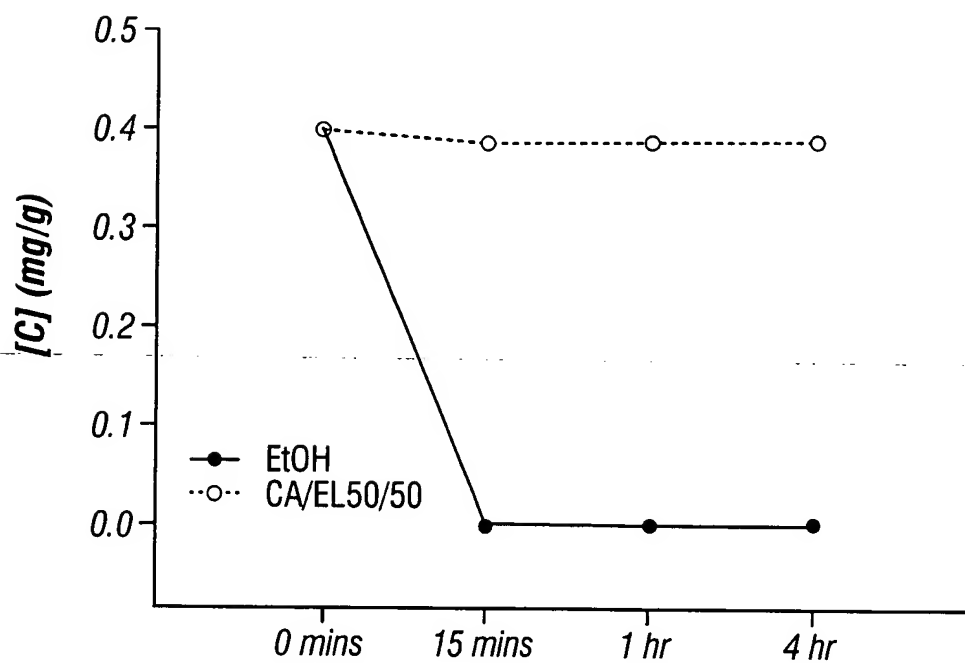
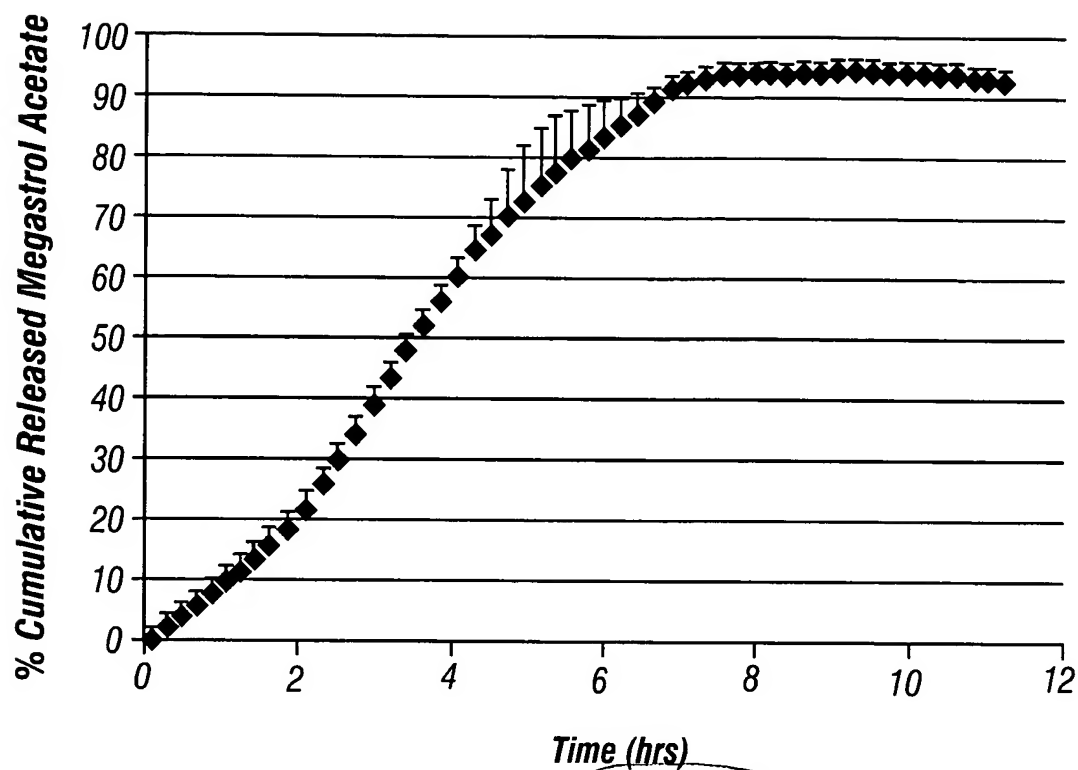


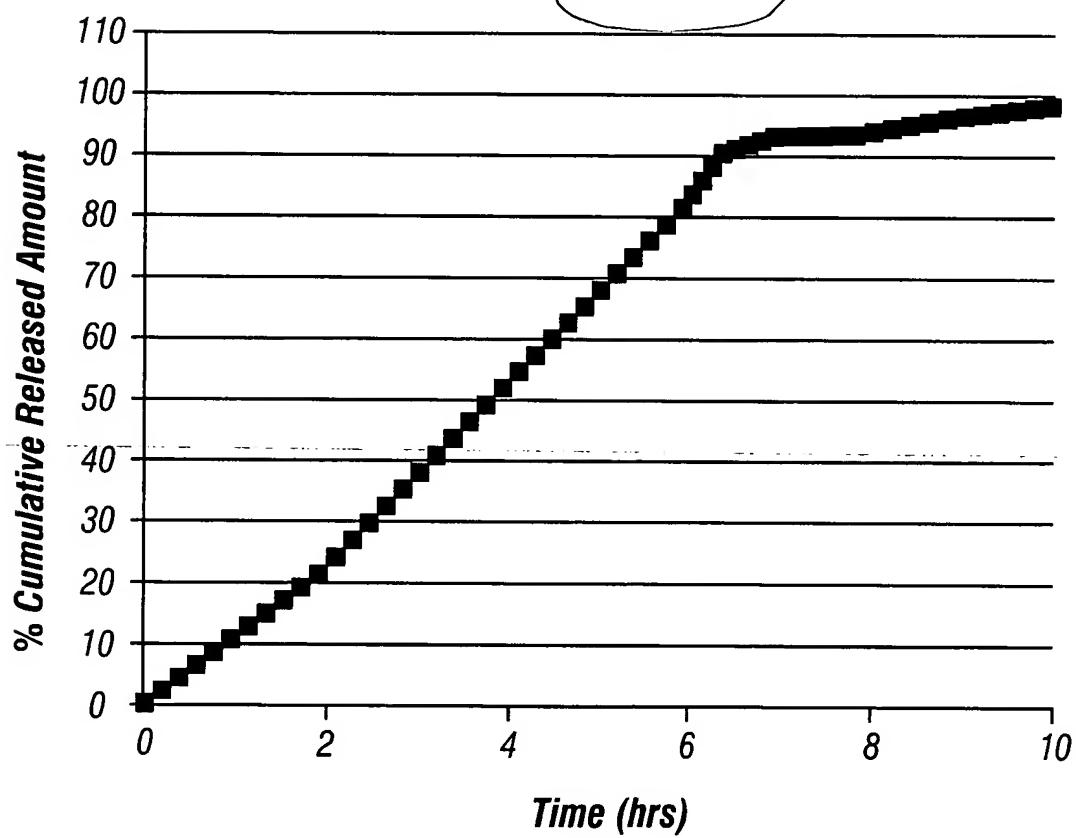
FIG. 17

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Time (hrs)

FIG. 18



Time (hrs)

FIG. 19

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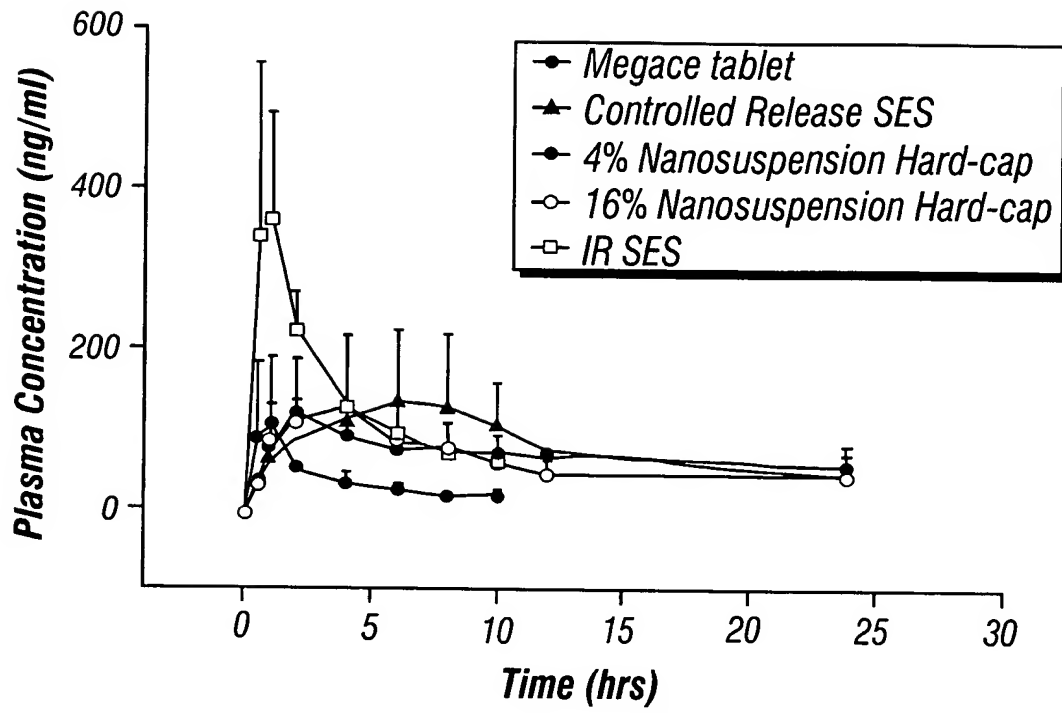


FIG. 20

Physical Properties of Various Saturated Fatty Acids

<i>Fatty Acid</i>	<i>Melting temperature (°C)</i>	<i>Solubility in water at 20°C(mg/g)</i>
<i>Caproic acid (C6)</i>	-3.4	10.82
<i>Caprylic acid (C8)</i>	16.7	0.68
<i>Capric acid (C10)</i>	31.4	0.15
<i>Lauric acid (C12)</i>	44	<i>Insoluble</i>
<i>Myristic acid (C14)</i>	58.5	
<i>Palmitic acid (C16)</i>	63-64	<i>Insoluble</i>
<i>Stearic acid (C18)</i>	69-70	<i>Very slightly soluble</i>

FIG. 21

**Composition of Dosage Megastrol Acetate Formulations
of Dosage Forms Used in Multi-arm PK Study**

	<i>Formulation</i>
<i>Megace Tablet (20mg)</i>	<i>Unknown</i>
<i>IR SES (10mg) x2</i>	<i>MA/Pluronic F108/Capric Acid/Cremophor EL (1.77/0.83/48.7/48.7, wt%)</i>
<i>Controlled Release SES (10mg) x2</i>	<i>MA/Pluronic F108/Capric Acid/Cremophor EL (1.77/0.83/48.7/48.7, wt%)</i>
<i>4% Nanosuspension Hard-cap (20 mg)</i>	<i>MA/Pluronic F108/Capric Acid/Cremophor EL (3.8/1.4/47.4/47.4, wt%)</i>
<i>16% Nanosuspension Hard-cap (20 mg)</i>	<i>MA/Pluronic F108/Capric Acid/Cremophor EL (16.0/4.2/39.9/39.9, wt%)</i>

FIG. 22

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Plasma Sample Analysis (LC-MS) Conditions

<i>HPLC Conditions</i>	<i>HPLC: Agilent 1100 (ID: LC-125) Column: MetaChem Polaris C18-A, 100x30mm, 3um. Guard Column: Metaguard Polaris C18-A, 4.6mm, 3um. Flow Rate: 0.35ml/min. Injection Volume: 40ul. Mobile Phase: Isocratic 60/40 CH₃CN/H₂O, 0.2% Formic Acid.</i>
<i>MS Conditions</i>	<i>MS: PE Sciex API 300 LC/MA/MA with Analyst Ion Source: TurbolonSpray Scan Type: Positive MRM. Curtain Gas: Nitrogen, 9. Nebulizer Gas: Nitrogen, 9. Ionspray Voltage: 5.0 kV. Declustering Potential: 22V. Collision Gas: Nitrogen, 2. Collision Energy: 15V. MRM: m/z 385.2 to 325.2 for MA, 400ms. M/z 315.1 to m/z 109.0 for internal standard, 400ms.</i>

FIG. 23